REMARKS

Claims 35 and 64-68 are pending in this application. In view of the following remarks, Applicants believe that the asserted rejections should be withdrawn and that all of the claims are in condition for allowance.

Claims 35 and 64-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,638,531 in view of Helmerhorst et al (hereinafter "the '531 patent"). The Examiner asserts that the present invention is drawn to pharmaceutical compositions and methods of use comprising the peptide LLFLLKKRKKRKY (SEQ ID NO: 9) and bone material in a pharmaceutical composition that is capable of containing antimicrobial peptides. Please note that in the Office Action, the Examiner then proceeds to provide a discussion of the asserted teachings of Haminishi et al., rather than of the '531 patent.

In order to assert a double-patenting rejection, a patent or patent application and the application at issue must have common ownership. Applicants point out that the present invention and the '531 patent are not commonly owned, as they are assigned to different assignees. Therefore, Applicants respectfully submit that an assertion of an obviousness-type double patenting rejection against this application in view of the '531 patent is not warranted and should be withdrawn.

With the expectation that the '531 patent will be asserted to be anticipatory prior art against the claimed invention, Applicants present the following remarks to clearly distinguish the '531 patent, as well as Haminishi, from the claimed invention.

The present invention is directed to a bone material, wherein particular antimicrobial peptides, namely SEQ ID NOs. 7, 8 and 9, have been incorporated. These antimicrobial peptides have a fast release profile with respect to known antibiotics.

In contrast, although the '531 patent discloses the antimicrobial peptides of SEQ ID NOs. 7, 8 and 9, they are not disclosed in the context of bone cement, and the '531 patent provides no incentive to one skilled in the art to incorporate the antimicrobial peptides of the claimed invention into bone cement.

The Examiner asserts that one skilled in the art would incorporate the antimicrobial peptides of the '531 patent in bone cement, based on the teaching of Haminishi. However, Haminishi teaches away from the claimed invention. At best, Haminishi discloses that several drugs can be incorporated in bone cement without denaturation (see, e.g., page 142, right column, lines 7-10). Specific examples of drugs are insulin and cephalexin (page 139, left column, line 16-18). Additionally, Haminishi describes the incorporation of vancomycin in bone cement in order to achieve local release of vancomycin over a specific period of time, which is desirable in combination with surgical removal of infected bony tissue (page 139, left column, lines 10-12). Most importantly, the last sentence of the introduction on page 139 describes the slow delivery of vancomycin for treatment of osteomyelitis. This slow delivery is necessary because systemic administration of vancomycin causes several negative side effects (see page 139, left column, lines 7-10). Thus, Haminishi discloses a slow delivery system for local release, as is shown in Figure 1, right panel and Figure 2. Furthermore, a fast release profile would not lead to a long-term antibiotic reaction, as envisaged by Haminishi, but rather would more or less mimic the undesirable systemic administration described by Haminishi. (The specification of the present application provides a discussion of such slow release systems at page 1, lines 6-23).

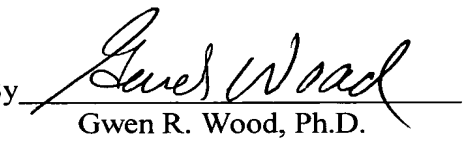
In contrast to the teachings of Haminishi, the claimed invention provides completely different antibiotic molecules, namely antimicrobial peptides of human origin, which show a fast release profile, as shown in WO 02/060503, Figure 4, a copy of which is attached herewith. In Figure 4, it can clearly be seen that more than half of the amount of the antimicrobial peptide, incorporated in bone cement, is released after one day. However, at best, Haminishi shows such a release after two days or more (see Figure 1, left panel, and Figure 2). Applicants submit that, based on the clear disclosure of Haminishi to provide a slow delivery system, it would not be obvious to one skilled in the art to incorporate in bone cement a novel antimicrobial peptide having a fast release profile. Additionally, because the antimicrobial peptides of the claimed invention are of human origin, better compatibility is obtained, and thus, unlike Haminishi, no surgical removal of infected bony tissue is required. Furthermore, no bacterial resistance occurs using the antimicrobial peptides of the claimed invention, whereas such resistance inevitably will occur using vancomycin according to the disclosure of Haminishi.

Applicants submit, therefore, that neither the '531 patent nor Haminishi, either alone or in combination, teaches or suggests the particular antimicrobial peptides of human origin of the claimed invention, namely SEQ ID NOs. 7, 8 and 9, incorporated in bone cement, in which the antimicrobial peptides have a fast release profile with respect to known antibiotics.

In view of the foregoing remarks, it is respectfully submitted that all pending claims 35 and 64-68 in the present application are distinguishable from the cited prior art. Accordingly, reconsideration and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

THE WEBB LAW FIRM

By 

Gwen R. Wood, Ph.D.
Registration No. 51,027
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, Pennsylvania 15219
Telephone: 412-471-8815
Facsimile: 412-471-4094
E-mail: webblaw@webblaw.com